The study involves cross-sectional analyses of 44,957 veterans and non-veterans enrolled in Medicare. Merged Medicare claims for fee-for service enrollees and survey data from multiple years of the Medicare Current Beneficiary Survey from 2001 through 2005. ACSH for thirteen conditions were identified using inpatient Medicare claims and an algorithm developed by the Agency for Healthcare Quality, which uses International Classification of Diseases, 9th edition codes. Dual use was defined as having inpatient or outpatient visits to the VHA and consisted of predominant-VHA use and some VHA use. Unadjusted group differences in any ACSH were tested using chi-square tests. Logistic regressions were used to analyze the association between dual VHA use and ACSH after controlling for demographic, socio-economic, health status, mental illness, smoking and obesity. All analyses accounted for the complex design of the survey. **RESULTS:** The three most common ACSH were congestive heart failure, bacterial pneumonia, and chronic obstructive pulmonary disease. Among inpatient users, 10.1% had ASCH for acute conditions and 15.8% for chronic conditions. Among all survey respondents, 5% had any ACSH; the rates were 4.9% for VHA users and 3.7% for veterans with some VHA use. In bivariate and multivariate analyses, dual use was not significantly associated with any ACSH. **CONCLUSIONS:** In a representative sample of Medicare beneficiaries, ACSH were prevalent. Despite poor health status, dual VHA/Medicare use was not associated with increased ACSH rates perhaps due to the provision of good primary care in the VHA system.

PIH38

EPIDEMIOLOGY OF ADOLESCENT AND YOUNG ADULT HOSPITAL UTILIZATION FOR ALCOHOL AND DRUG USE, SUICIDE, AND POISONING IN THE UNITED STATES

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OBJECTIVES: Adolescence and young adulthood are an important transitional period during which morbidity and mortality often arise from individual's behaviors such as alcohol and drug use, suicide, and poisonings. Self-report survey data regarding health behaviors are readily available, however little data from objective sources has been reported and minimal study of health care utilization, particularly hospital utilization, related to these behaviors has been conducted. This study examines the patterns and characteristics of individuals admitted to the hospital for these conditions. **METHODS:** The data for this investigation came from the 2007 National Hospital Discharge Survey (NHDS). Records for all individuals who had an age in the range of 10-24 years and were discharged from the hospital with any recorded diagnosis of alcohol or drug abuse or dependence, suicide, or poisonings were abstracted. National estimates were calculated utilizing the weighted number of discharges and the U.S. Census Bureau population data for this age group. Rao-Scott Chi square tests were performed to evaluate differences between groups and all significance tests were two-sided using $p<0.05$ as the level of statistical significance. **RESULTS:** National estimates for hospital discharges per 1,000 10-24 year olds are 54.2 for alcohol/drug use, 3.3 for suicide, and 9.8 for poisoning. Seasonal trends in alcohol/drug and suicide discharges were observed, as were regional differences with more than twice as many alcohol/drug-related discharges in the South. Over 42% of all care related to these diagnoses is expected to be paid for by public health insurance programs. Self-pay is also high for these conditions (16.1%). **CONCLUSIONS:** A significant porition of inpatient hospital care for adolescents and young adults is attributable to alcohol/drug use, suicide, and poisonings. These data have implications for primary intervention programs and suggest the need for further investigation of the associated health care costs related to these conditions.

PIH39

THE EFFECT OF ELECTRONIC-MEDICAL-RECORD SYSTEM SOPHISTICATION ON PREVENTIVE HEALTH CARE FOR WOMEN

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OBJECTIVES: Electronic-medical-record (EMR) systems have the potential for improving the quality of preventive healthcare for women, by reminding patients and physicians to obtain appropriate screenings and vaccinations, and decrease health-care costs significantly by preventing emergency-department visits and hospitalizations. The objective was to study the effect of EMR-system sophistication on women's healthcare in physician offices. **METHODS:** The National Ambulatory Medical Care Survey (NAMCS), a cross-sectional database of physicians' office-based visits was analyzed. Based on several of the NAMCS questions, EMR-systems were classified into nonexistent, minimal, basic, and fully functional systems according to their set of specific functions. Visits were selected provided that (1) they were made by a woman > 18 years old and (2) the visit was not for a chronic or acute illness as identified by the visit's ICD-9 code. Preventive healthcare provision included screenings (mammography and bone-mineral-density imaging); exams (breast and pelvic); tests (PAP tests and tests for chlamydia, cholesterol, and blood pressure); and vaccinations. Estimated frequencies of preventive health services ordered or completed by the physician were for the four levels of EMR-system sophistication. **RESULTS:** In 2007-08, 341,729 physicians ordered or provided 2.56, 1.31, 1.97, and 1.82 million preventive healthcare exams, screenings, tests, and vaccinations for women aged 18-39, 40-49, 50-64, and >65, respectively. The ratios of number of preventive women's healthcare measures to number of visits by women, for practices with no EMR were the lowest (1.12, 1.21, 1.25 and 0.28 for age-groups 18-39, 40-49, 50-64, and >65, respectively). Whereas, practices with fully-functional EMR systems had the highest ratios, (1.5, 1.54 and 0.48 for age-groups 18-39, 50-64 and >65, respectively), except for the 40-49 age group, for which minimal-EMR-system practices had the highest ratio of 1.61. **CONCLUSIONS:** Evidence suggests that the more sophisticated the EMR system, the greater the intensity of preventive healthcare service provided to women.

PIH40

RETROSPECTIVE DATABASE ANALYSIS OF TREATMENT PATTERNS AND HEALTH CARE COSTS AMONG WOMEN WITH IDIOPATHIC HEAVY MENSTRUAL BLEEDING

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OBJECTIVES: Assess real world treatment patterns, health care utilization, and costs of HMB patients. **METHODS:** Data were administrative claims from a large national US health plan. Female plan enrollees aged 18-49 with at least 2 claims of HMB (ICD-9-CM 626.2, 627.0) within 180 days during 01-01-04 to 02-29-08 were included; index date was initial HMB claim. Continuous enrollment required 6 mos pre-index and 18 mos post-index. Patients were classified as idiopathic HMB unless underlying conditions associated with HMB occurred in pre-index or 60 days post-index date. All variables were analyzed descriptively. Multivariate analyses were conducted to evaluate the factors associated with follow-up HMB-related costs. **RESULTS:** Mean [SD] age of the study population (N=21,239) was 39.5 [6.8]; mean [SD] comorbidity score was 0.14 [0.42]. Of the 21,239 women, 57.6% had 1 treatment episode, 15.7% had 2 or more, and 26.6% had no treatment during the post-index. 15,582 patients received treatment, the distribution of initial treatment was 36.4% received medication (oral contraceptive [OC], non-OC, or oral medroxyprogesterone acetate [MPA]), 50.8% had endometrial ablation [EA], and 12.6% underwent hysterectomy. Mean [SD] HMB-related costs of single episode paths were: hysterectomy $8,656.84 [$5,453.34]), EA $4,579.63 [$3,509.16], and no treatment $616.23 [$946.73]. On average follow-up HMB-related costs are expected to be 9.67 times greater for women with multiple episodes and 6.33 times greater for single episode (ref. group: no treatment). Age, Charlson comorbidity score, geographical region were also associated with higher total follow-up HMB-related costs whereas baseline OC use and pregnancy during the follow-up lowered costs. **CONCLUSIONS:** HMB has significant clinical and economic impact. Over 1/4 of patients did not receive treatment. Prevalence of surgical procedures was high among those treated, often constituting first-line treatment. Surgical procedures and multiple treatment episodes were associated with higher HMB-related costs.

Individual's Health – Research on Methods

PIH41

SUCCESSFUL SEXUAL INTERCOURSE: TIME-TO-EVENT MODELING IN A SILDENAFIL TRIAL

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OBJECTIVES: Patients with unmet expectations for the time required to experience improvement (or sustained improvement) with treatment may prematurely discontinue otherwise effective treatment. We assessed median time to successful sexual intercourse (SSI) with sildenafil and placebo. **METHODS:** Successful sexual intercourse was assessed in an 8-week, double-blind, placebo-controlled trial of sildenafil treatment in men with erectile dysfunction. SSI for each episode of sexual activity was defined by patient report and by two events: 1) the subject attempted sexual intercourse and 2) the subject had an erection lasting long enough for successful intercourse. Median time to SSI was calculated for two types of events: 1) time to the first SSI (transient event) and 2) stable SSI (initial improvement sustained for the remainder of the double-blind 56-day study, defined as at least 50% of sexual intercourses being successful until the end of the study). Log-rank tests compared time-to-event curves between treatment groups. **RESULTS:** Of 288 men enrolled, 95 received placebo, 99 received sildenafil 100 mg, and 94 received sildenafil 50 mg. Median time from the start of the study to achieve initial SSI was 3 days for each group of sildenafil-treated patients (50 mg and 100 mg), compared with 13 days for placebo-treated patients ($P<0.001$). (Note that not everyone attempted sexual intercourse on the first day of treatment.) Median time to achieve stable (sustained) SSI was 5 days (50 mg) and 3 days (100 mg) for sildenafil-treated patients versus 55 days for placebo-treated patients ($P<0.001$). **CONCLUSIONS:** This novel application of time-to-event analysis provides useful timeframes for when patients can expect to see initial and then stable improvements with sildenafil treatment. Median times to initial SSI and sustained SSI were significantly shorter for sildenafil-treated vs placebo-treated men.

PIH42

A NET BENEFIT FRAMEWORK (NBF) ANALYSIS OF CHART DATA FOR HAEMOPHILIA INHIBITOR PATIENTS

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OBJECTIVES: Effective treatment of bleedings in hemophiliac patients is important for limiting costs associated with bleedings and for improving health outcomes. Two health outcomes of interest is the time from treatment initiation to bleeding resolution and the probability of developing re-bleedings. The objective of this study was to develop a methodology with NBF instead of the ICER for estimating the health economic benefits of a novel treatment with certain characteristics compared to rFVIIa and to identify the major determinants of the net monetary benefit of the novel treatment. **METHODS:** Data from a medical chart review on hemophilia inhibitor patients in Turkey were used to identify predictors of the

amount of rFVIIa used to achieve haemostasis. A Generalized Linear Regression Model was used to derive the potential cost-offsets of a novel treatment. The net monetary benefit per bleeding treated of the novel treatment compared to rFVIIa was estimated using a variety of assumptions on the efficacy of the novel treatment as well as on the valuation of the health benefits. **RESULTS:** Assuming a reduction in time to bleeding resolution by 25%, a novel treatment saved €339 per bleeding compared to rFVIIa. Including the value of the health benefits, which were estimated to €51, the net monetary benefit of the novel treatment was €390 per bleeding. The results were sensitive to assumptions around the efficacy of the new treatment but also around the valuation of health benefits. **CONCLUSIONS:** A novel treatment which reduces time to bleeding resolution would entail important health economic benefits, both in terms of health care cost-offsets and health benefits. One limitation of cost-effectiveness analyses in hemophilia is the uncertainty around the valuation of short term health benefits.

PIH43

METHODOLOGY TO IDENTIFY IN-VITRO FERTILIZATION PATIENTS USING A NATIONAL MANAGED CARE DATABASE

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BACKGROUND: The majority of analyses of outcomes related to fertility treatments are conducted in datasets from fertility centers. To date there has been no established methodology for identifying fertility protocols in payer databases. **OBJECTIVES:** To identify a methodology for identifying fertility protocols in a national administrative claims database. **METHODS:** This retrospective descriptive study used PharmMetrics, a national managed care dataset. Patients with at least one prescription for a gonadotropin-releasing hormone agonist (GnRHAg) or antagonist (GnRHAnt) between January 1, 1999 and May 31, 2009 were selected. Drugs billed with a National Drug Code were included and were identified using generic product identifiers. Index date was set as the first pharmacy claim date for a GnRHAg or GnRHAnt. Patients were excluded if no prescription record for FSH existed in the 7 days pre-index through 60 days post-index and HCG in the 60 day post-index period. Patients must be eligible for services for 12 months before and after the index date, which established continuous eligibility for services. Longer eligibility allows assessment of outcomes such as birth rates. The final sample consisted of patients with an embryo transfer code within 60 days of index. Outcome of delivery codes served as indicators for live birth if they occurred within 294 days (42 weeks) after transfer date. **RESULTS:** Inclusion and exclusion criteria were applied to patients that had at least one prescription for GnRHAnt or GnRHAg, resulting in some attrition of sample (880 patients with IVF). The 2-year continuous eligibility requirement accounted for the largest number of patients removed. **CONCLUSIONS:** Administrative claims data provide a large sample of IVF patients, but are limited in some analyses due to a lack clinical details. The proposed methodology was able to successfully identify IVF treatment cycles and link these to delivery outcomes for treated patients under real-world conditions.

PIH44

MULTIDOMAIN LONGITUDINAL MODELING: APPLICATION TO THE INTERNATIONAL INDEX OF ERECTILE FUNCTION

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OBJECTIVES: Individual domains of multidomain patient-reported outcome instruments typically are analyzed independently, without considering inherent dependency of component domains. This report presents an underused modeling approach that accounts for correlations across time (longitudinal) and correlations across domains of a multidomain instrument in one integrated model. **METHODS:** International Index of Erectile Function (IIEF) data from a double-blind placebo-controlled trial of fixed-dose sildenafil (50 or 100 mg) in 288 men with erectile dysfunction were used. Standard methodology was used for the individual-domain longitudinal model. This model was then expanded to account for relationships among domains for the multidomain longitudinal model, performing modeling of treatment effects on all domains simultaneously. Covariance was constructed by taking the Kronecker product of an unstructured covariance matrix across domains (modeling covariance across the domains) with an unstructured covariance matrix across time (modeling covariance across time). Analyses were performed with Proc Mixed using SAS v9.2. **RESULTS:** The model was constructed and fitted, which integrated all IIEF domains simulataneously into one unified multidomain longitudinal model. Treatment effects for all 5 IIEF domain scores calculated using individual or multidomain modeling were similar, reflecting the robust application of IIEF data in this study. **CONCLUSIONS:** Modeling correlation structure simultaneously across domains of a multidomain instrument, as well as across time, more rigorously addresses the interrelationship between domains and potentially presents a more accurate estimation of efficacy and statistical inferences. Additional work with simulations and more empirical evidence are needed to better understand the multidomain longitudinal model.

PIH45

MULTILEVEL ANALYSIS TO MEASURE HOSPITAL VARIATION: THE CASE OF CESAREAN DELIVERY

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OBJECTIVES: Efficiency in health systems is often a matter of concern and differences on the expected productivity of a given procedure might lead to inefficient variations in the performance of such interventions. Health economics literature has extensively revisited the topic of variations in health care using multivariate models to predict variation across geographic regions. The clustering effect of facilities (as a functional unit), however. has not been described before. This analysis examines the extent to which facilities explain geographic variation in health care. **METHODS:** A set of individual data on all births from a Contributory-Regimen insurer in Colombia was assessed. We performed a multilevel logistic regression model, taking hospitals as the clustering variable. In addition, we included an alternative variance decomposition specification to estimate the attributable effect of geographic region on the variability across hospitals. We used a set of variables including mother education and income, physician fees, and complications during pregnancy to control for in this analysis. **RESULTS:** Our results reveal that hospitals account for 20% of variation on the probability of performing cesarean sections. Geographic area only explains one-third of the variance attributable to the hospital. In addition, physician fees (0.077; SE 0.023), mother's income (0.070; SE 0.014) and superior education in mothers (0.299; SE 0.107). This supports the effect of mother and physician preferences on variations. **CONCLUSIONS:** This paper contributes to previous research by using a multilevel model approach and by defining hospitals as cluster. We found a strong effect of hospitals on determining variations. In addition, we found how supply-side factors such as physician fees and demand-side factors (proxies for preferences) such as mother's education and income are affecting variations across hospitals and regions. The effect of facility as well as individual-level variables should be taken into account when researching on variations in health care.

PIH46

SPECIAL PRECAUTIONS TO CONSIDER WHEN PERFORMING COGNITIVE DEBRIEFING OF SENSITIVE TOPICS

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OBJECTIVES: The linguistic validation and cognitive debriefing of PROs are now well documented and routinely used within the pharmaceutical industry to ensure that the translated instruments are conceptually equivalent to their sources. Increasingly, new adjustments are being developed to further customize these processes according to the special needs of the instrument and target culture. This paper seeks to enumerate the challenges faced when debriefing questionnaires of an embarrassing, and potentially offensive, nature and recommends the use of a specialized methodology to make respondents more comfortable during this process. **METHODS:** To establish guidelines for debriefing PROs of a sensitive nature, subject feedback from previous ED questionnaire debriefing reports was examined. The subjects that expressed the most discomfort during the debriefing process resided in India, Africa, and the Middle East. Additionally, older subjects and subjects with lower levels of education were more likely to express reservations. For this study, we collaborated with translators from each of these regions to determine a list of measures that can be taken to help ensure that subjects feel comfortable enough to provide reliable feedback within the interview setting. **RESULTS:** The goal of any cognitive debriefing session is to adequately test the translated questionnaire while maintaining the cultural sensitivities of the target country. Recommended considerations include: assigning an interviewer of the same sex as the subject, performing a specialized training session with interviewers that reviews subjects' boundaries and strategies for effective probing, sending subjects an introductory note that emphasizes confidentiality prior to the interview, conducting interviews via telephone rather than in-person, and debriefing questionnaires via a web-based device. **CONCLUSIONS:** For some cultures, cognitively debriefing PRO questionnaires of a sensitive nature places added burden on respondents. Evidence suggests that additional considerations should be exercised during debriefing to respect subjects' cultural boundaries.

Infection – Clinical Outcomes Studies

PIN1

VACCINE-ASSOCIATED GUILLAIN-BARRE SYNDROME: A PHARMACOVIGILANCE ANALYSIS OF DATA IN THE UNITED STATES' VACCINE ADVERSE EVENT REPORTING SYSTEM (1990-2009)

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OBJECTIVES: To describe reporting rates and characteristics of vaccine-associated GBS reports in the Vaccine Adverse Event Reporting System (VAERS) over a two-decade period. **METHODS:** Adverse event reports submitted to VAERS from January 1990 to November 2009 are utilized to conduct a retrospective pharmacovigilance analysis by calculating the proportional reporting ratios (PRR) and corresponding 95% confidence intervals (CI) for vaccine-GBS event pairs. **RESULTS:** One thousand and 259 reports of vaccine-associated GBS are identified for 37 vaccines. The mean age of patients experienced GBS after vaccination was 31 years; 51% of patients were females. Majority of the reports were for influenza (FLU) (791) and hepatitis B (HEP) virus vaccines (103). Reports for human papillomavirus quadrivalent (HPV4), meningococcal conjugate (MNQ), and measles/mumps/rubella (MMR) virus vaccines accounted for 37, 36, and 34 reports, respectively. Death, disability and hospitalization among the serious GBS outcomes were correspondingly reported in 36 (2.9%), 199 (15.8%), and 963 (76.4%) reports. Most of these outcomes were in FLU reports. The average postvaccination GBS onset delay was 3.5 weeks; ranging from 2.3 weeks for FLU to 8.1 weeks for MNQ. About 79% and 12% of GBS reports included